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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/209,323 12/11/98 GINES

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EXAMINER

QM12/0322

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UNITED STATES SURGICAL CORPORATION
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ART UNIT	PAPER NUMBER
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3739

DATE MAILED:

03/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/209,323

Applicant(s)

GINES, DAVID LEE

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 1998.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 17) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other:

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-16 are rejected under 35 U.S.C 112, first paragraph, for undue breadth since these claims are drawn to a single means.

Claim 12 sets forth only a means for minimizing tissue, with no other structure or elements in combination therewith. Also, dependent claims 13-16 fail to set forth any further structure. Rather, these claims recite various intended functions without the necessary structure for performing the functions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 lacks proper antecedent basis for "the controller" at line 2. This claim is also unclear with the scope of the invention since it appears an electrosurgical generator is the subject matter of the invention, but the preamble recites "the controller

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comprising". It is assumed "the controller" in line 2 should read "the electrosurgical generator".

Claim 12 fails to provide sufficient structure to support the functions set forth. In particular, claim 12 indicates that the controller adjusts output in response to the degree of desiccation; however, there is no means for the controller to monitor or otherwise receive indication of a degree of desiccation.

Likewise, claims 13-16 recite various functions that lack sufficient structure to support the performance of the functions. In claim 13, there is no means to terminate the output power. Claim 14 fails to provide means or structure to determine tissue impedance. Claim 15 fails to provide means to adjust output voltage, and claim 16 fails to provide a particular structure or means to repeatedly increase and decrease output power.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-6, 8, 9 and 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller, III ('943).

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Miller provides an electrosurgical generator whereby energy delivery to tissue is controlled in response to monitored tissue impedance. In particular, tissue impedance is measured, and a controller (70) cycles the output power (i.e. increases, decreases or shuts off the power). Column 12, line 40 through column 13, line 36 of the Miller patent discloses the impedance control means. With regard to the frequency at which the output power is cycled, the examiner maintains that depending on the measured impedance characteristics, the output power would be cycled at any necessary frequency which would inherently include very low frequencies. That is, if there is only slight changes in tissue impedance over a given span of time, the output power will be changed infrequently (i.e. at a low frequency). The Miller controller is also a "means for minimizing the burning of tissue" as set forth in applicant's claim 12, and the system performs the functions as set forth in applicant's claims 13-16.

Claims 1-7, 8, 9 and 12-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Yates ('671).

Yates also provides an electrosurgical system with an impedance measuring means, and a controller to control the output power in accordance with measured impedance. The measured tissue impedance is compared to a desired impedance range, and the output power is cycled accordingly. Again, the frequency at which the output power is cycled is a function of the tissue impedance variation and may inherently be very low. Yates also discloses a means to operate the system whereby

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the voltage and current are controlled to maintain a desired power profile to treat tissue (see column 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller, III ('943) in view of the teaching of Yates ('671).

The Miller system has been addressed previously. Miller fails to disclose the particular output voltage used. The examiner maintains that the known range of applied voltages in such electrosurgical systems is very well known in the art, and one of ordinary skill in the art would certainly recognize that 120 volts may be a maximum desired output. In support of this contention, Yates discloses a voltage range of from 30-200 volts (column 6, lines 16-17). Also, Yates discloses a means to operate the system whereby the voltage and current are controlled to maintain a desired power profile to treat tissue (see column 9).

To have provided the Miller system with any desired and well known voltage range would have been an obvious consideration for one of ordinary skill in the art. To have further provided the Miller system with a means to control power and current delivered to tissue to maintain a desired (i.e. constant) power profile would have been

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an obvious modification for one of ordinary skill in the art in view of the teaching of Yates.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are rejected under the judicially created doctrine of double patenting over claims 1-23 of U. S. Patent No. 6,033,399 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: an electrosurgical generator for controlling the delivery of energy in response to tissue impedance.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of

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the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cohen et al ('396), Sherman ('980), Edwards et al ('975), Behl et al ('717), Cordis et al ('443) and Klicek ('312) disclose various electrosurgical generators which control energy delivery to tissue based on sensed tissue impedance.

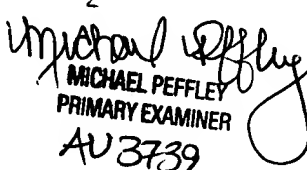
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on 9 hour.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda M Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley/mp
Primary Examiner
Art Unit 3739
March 20, 2000


MICHAEL PEFFLEY
PRIMARY EXAMINER
AU 3739